PATENT SPECIFICATION

(11) 1 558 111

(21) Application No. 34981/77 (22) Filed 19 August 1977
(44) Complete Specification Published 19 December 1979
(51) INT. CL.^{2} A61B 5/05
(52) Index at Acceptance G1N 19B1B 19B2Q 30P0
(72) Inventor LAJOS PAPA

1 558 111

(19) THE PATENT OFFICE LONDON

(54) METHOD AND SENSOR DEVICE FOR DETECTING THE LOCATION AND/OR CHARACTER OF A LESION IN BODY TISSUE

(71) We, RADELKIS ELEKTROKÉMIAI MŰSZERGUÁRTÓ SZÖVETKEZET, of 1 Laborc-utca, Budapest III., Hungary, a body corporate organized under the laws of Hungary, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed to be particularly described in and by the following statement:—

The invention relates to a method for detecting the location and/or character of a lesion in the body tissue in the course of which electrodes are put onto or into the said tissue, and an electric measuring device is connected to the said electrodes in order to measure the electric parameters or features of the said tissue. The invention further relates to a sensor device for the performance of the said method, comprising an electric measuring device and a pair of measuring electrodes.

Under the title "The modification of the electrolyte equilibrium in the malignus proliferation of the skin", a survey was published in September, 1969 in the medical journal Magyar Onkológia on the recent research accomplishments and the literature sources concerning the establishing of lesions in the tissue of the body.

The publications disclose the so-called resistance measuring or impedance measuring method for the detection of lesions in the tissue of the body or malignus. One of the most up-to-date versions of this method consists in a square-wave pulse being supplied to the surface of the deformed tissue, the pulse penetrating through the said tissue to a sensor electrode and appearing on the screen of an oscilloscope coupled to the said electrode, this signal then being evaluated. The displayed waveform is characteristic of the impedance of the tissue of the body. The method as set forth above is suitable for the diagnostic establishment of lesions in the surface of the tissue. It is disadvantageous that its application is restricted to the detection of surface lesions;even if the electrodes penetrate the body or its cavities, no reliable, valuable detection of lesions can be obtained since it is the laminar cuticle the decay of which causes a change in the capacitive component of the impedance.

The examination of the tissue of the body and especially the methods applied in the diagnosis of tumours are rather sophisticated and time-consuming. The minimum duration of a conventional histological examination amounts to 24 hours. Although the examination of quickfrozen excisions can be performed within only 10 minutes or so, such a method can only be performed successfully by experts with specialist skills in this field since the quick-freezing process destroys the cells.

A well-known diagnostic method is the one utilizing radioactive isotopes but for this purpose expensive equipment is needed and furthermore there is the disadvantage of radiation damage.

Thermometric examinations are not suitable because of their lack of reliability.

Ultrasonic examinations can detect the location of lesions in tissues but no information can be obtained concerning the character of the said lesion.

The uncertainty in establishing a tumour is 17,5% for X-ray examinations, 39% for gastroscopy, and 21% for cytology.

It has already been mentioned that the measurement of the resistance or the conductivity according to prior art is only suitable for the detection of lesions appearing at the surface of the skin or in tissue covered immediately by cuticles; the measured value is affected by many factors such as the structure of the tissue, and the state of the surface of the tumour, i.e. whether the surface is intact or not.

The invention aims to make it possible to

establish the location and/or the character of a lesion in body tissue by a diagnostic method, and to provide a sensor device suitable even in cases when the tumour is embedded in the tissue of the body, the device being quick and reliable to operate without the need of a sample excision.

The invention is based on the realisation that such a diagnostic method can be found if utilising a special feature of the tissue, viz. the fact that the electrolytic strength of the malignus tissues is of a higher value than that of sound tissue. It has been realised that two electrodes of different substances and electrode potentials if put into the said tissue—may be considered to form a primary cell supplying a potential that is in itself not characteristic of the electrolytic concentration of the tissue on open circuit of the cell. However the ability of the cell to provide sustained current is dependent on the electrolytic concentration of the tissue.

According to one aspect of the invention there is provided a method for detecting the location and/or character of a lesion in living tissue, wherein two electrodes of differing electrode potentials are placed onto or into the tissue the electrodes being connected to the terminals of an electric current measuring device which has a small internal resistance such that the current flowing through the device and between the electrodes is measured by the device and is representative of the electrolytic concentration of the tissue between the electrodes.

It is expedient to compare the measured value of the current flowing between the electrodes with the value measured in the same manner on a piece of sound tissue.

The sensor device suitable for the performance of the said method comprises two electrodes having differing electrode potentials and a current measuring device for connection across the electrodes when the latter are placed into or on the tissue, the electrodes being provided by either:—

(i) two electrically conducting, concentric members separated by electrically insulating material with one end of the inner member being exposed to form one electrode surface and the corresponding end of the outer member forming the other electrode surface, the extremity of said one end of the inner member being coplanar with or projecting beyond the extremity of said one end of the outer member or,

(ii) two pivotally interconnected jaws of a sample excision spoon, the parts being pivotally mounted on an insulating stem of the spoon.

It is an advantage of the method and the sensor device according to the invention that the location and the character of tumours embedded in body tissue can immediately and reliably be established without the need of making a sample excision. This way it is possible to detect lesions also by endoscopy, puncture or biopsy.

The invention will now be set forth more particularly with reference to the accompanying drawings showing preferred embodiments of the sensdor device.

Figure 1 shows a sensor device adapted from a medical syringe.

Figure 2 shows a sensor device adapted from a sample excision spoon with open jaws whereas Figure 3 shows the sensor device of Figure 2 but with closed jaws.

It can be seen in Figure 1 that the diagnostic sensor device according to the invention utilizes a tubular medical syringe 1 itself. One of the electrodes of the sensor device is formed by the metal syringe 1 itself. Inside the tube of the syringe 1 is an inner electrode 3 with insulating material 2 disposed between the syringe 1 and the electrode 3. The inner electrode 3 is of a different substance from that of the syringe 1, i.e. their electrode potentials as compared with that of hydrogen are different. If the syringe 1 is made of stainless steel, the inner electrode 3 can e.g. be made of magnesium or carbon. The insulating material 2 is "Teflon"® . The active end surface of the inner electrode 3 can be arranged in the same plane as the end surface of the insulating material 2 and the end of the syringe 1, or it can project from the syringe. The syringe 1 and the electrode 3 are coupled to the input terminals of a current meter 7.

Figures 2 and 3 show another embodiment of the sensor device according to the invention. The sensor device is adapted from a sample excision spoon as known in the prior art. Two jaws 4 and 5 of the said spoon (forming electrodes) are pivotally mounted on an insulating stem 6, and the jaws 4 and 5 are made of different metals the electrode potentials of which (as compared with that of hydrogen) are different. The jaws 4 and 5 are provided with terminals led through the insulating stem 6 and coupled to the input terminals of the current meter 7.

The sensor devices as set forth above can advantageously be applied for performing the diagnostic method according to the invention. The essence of the method according to the invention consists in that the two electrodes of different materials are put onto or into the body tissue, the electrodes are connected across a measuring device having a small internal resistance and the substantial current flowing through the terminals of the said electrodes is measured, whereupon the measured value of the

current flowing between the electrodes may be compared with the value measured in the same way on a piece of sound tissue.

The method is based on the phenomenon that the electrolytic strength of malignus tissues is higher than that of sound tissue. The electrolyte is utilized as the electrolyte of the primary cell constituted by the said electrodes led into the tissue. The ability of the primary cell to produce current is characteristic of the electrolytic strength. Theoretically, the open-circuit voltage of the primary cell is independent of the electrolytic strength. In practice however, even without external load, some dependence of the cell voltage on electrolytic strength can be explained by the fact that the internal resistance of the body itself constitutes a load on the primary cell established within the tissue of the body. This load effect is to a great measure determined by the dimensions and arrangement of the electrodes, by the volume of the tissue surrounding the said electrodes, and the electrolytic strength.

The uncertainty caused by the said internal conductivity of the body is compensated if the electrodes are connected to the measuring device.

The electrodes can be made of any good electrical conductor (e.g. metal) provided that they are of different materials. The e.m.f. of the primary cell is dependent on the distance of the two metals from each other in the electrochemical series; the greater the distance the greater the voltage drop that can be permitted over the current meter 7.

The sensitivity of the current meter 7 coupled between the electrodes is to be chosen in dependence on the substance and the dimensions of the electrodes. If, e.g., the sensor device as shown in Figure 1 comprises an external electrode 1 of stainless steel, and the diameter of the tube amounts to 1 mm whereas the inner electrode consists of magnesium and the active end surface is a circle of 0.8 mm diameter, then a sound mycoderm of the stomach effects a current of about 130 – 140 μA whereas a stomach adenocc. causes an increase of this current to about 220 – 230 μA. If one increases the active surface of the magnesium electrode, a proportional increase of the galvanic current established in the tissue can be obtained.

The method according to the invention can be applied in the field of skin tumour diagnostics, laryngology, gynaecology, and combinable endoscopic examinations. The method is suitable not only for the detection of permanent lesions in the tissue but even transitional changes in the state of the tissue can be detected and, thus, quick modifications in the process of life can be recognized such as the prospective date of childbirth or a danger menacing the foetus by examining the surface of the caul. The method can be applied in order to detect, the state preceding the cancerosis in the tissue of the body. The method makes it possible to draw conclusions concerning the state of the space inside the cell, e.g. loss of fluid in case of internal haemorrhage, inflammatory oedema by examining the surface mycoderms in the mouth or on the tongue. The time necessary to make a diagnosis—if applying this method—is diminished from hours to seconds and the result is even more exact than in the case of microscopic examinations. If one standardizes the electrodes and the measuring conditions, the malignus process can also be characterized by the absolute value of the current.

The location of the lesion in the tissue of the body can e.g. be established by inserting the electrodes in sequence at different points into the tissue and reading the current values the change of which shows the boundaries of the abnormal tissue.

WHAT WE CLAIM IS:—

1. A method for detecting the location and/or character of a lesion in living tissue, wherein two electrodes of differing electrode potentials are placed onto or into the tissue, the electrodes being connected to the terminals of an electric current measuring device which has a small internal resistance such that the current flowing through the device and between the electrodes is measured by the device and is representative of the electrolytic concentration of the tissue between the electrodes.

2. A method according to claim 1, wherein the measured value of current flowing between the electrodes is compared with a value of current measured in a comparable manner between similar electrodes placed onto or in sound tissue.

3. A sensor device when used in the method of claim 1 or claim 2, comprising two electrodes having differing electrode potentials and a current measuring device for connection across the electrodes when the latter are placed into or on the tissue, the electrodes being provided by either:—

(i) two electrically conducting, concentric members separated by electrically insulating material with one end of the inner member being exposed to form one electrode surface and the corresponding end of the outer member forming the other electrode surface, the extremity of said one end of the inner member being coplanar with or projecting beyond the extremity of said one end of the outer member, or

(ii) two pivotally interconnected jaws of a sample excision spoon, the parts being pivotally mounted on an insulating stem of

the spoon.

4. A method according to claim 1 substantially as herein described with reference to and as shown in Figure 1 or Figures 2 and 3 of the accompanying drawings.

5. A sensor device according to claim 3 substantially as herein described with reference to and as shown in Figure 1 of the accompanying drawings.

6. A sensor device according to claim 3 substantially as herein described with reference to and as shown in Figures 2 and 3 of the accompanying drawings.

T. Z. GOLD & COMPANY,
Chartered Patent Agents,
European Patent Attorneys,
9 Staple Inn,
London WC1V 7QH.
Agents for the Applicants

Printed for Her Majesty's Stationery Office by MULTIPLEX techniques ltd., St. Mary Cray, Kent. 1979. Published at the Patent Office, 25 Southampton Buildings, London WC2 1AY, from which copies may be obtained.

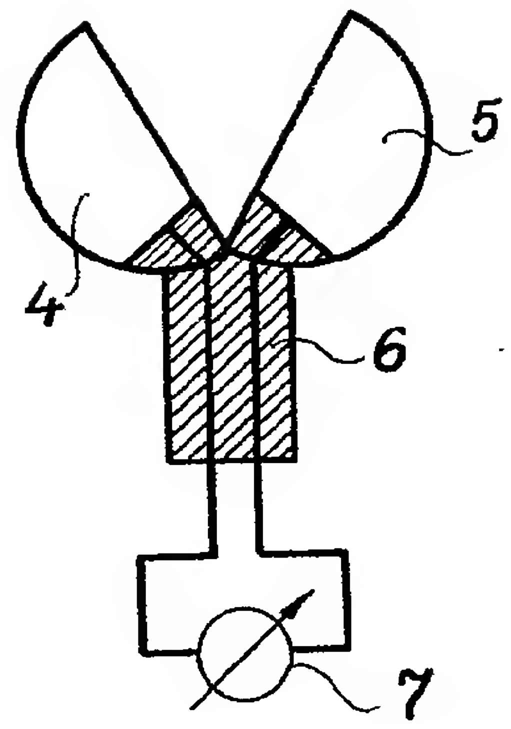

Fig. 2

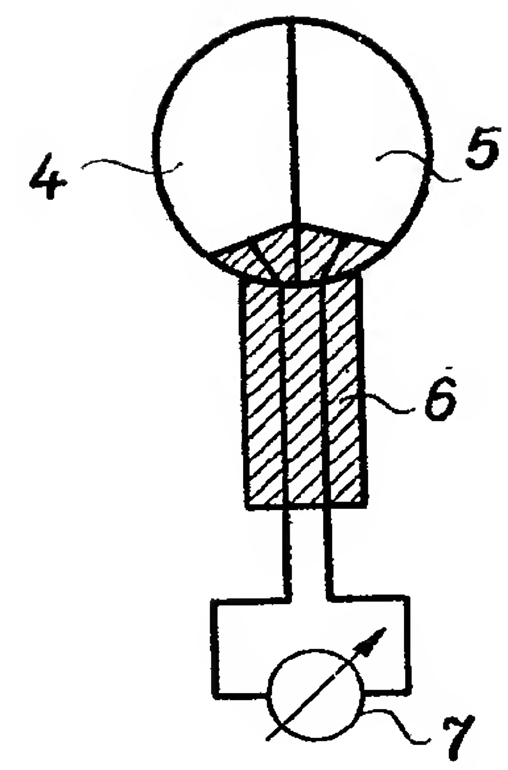

Fig. 3

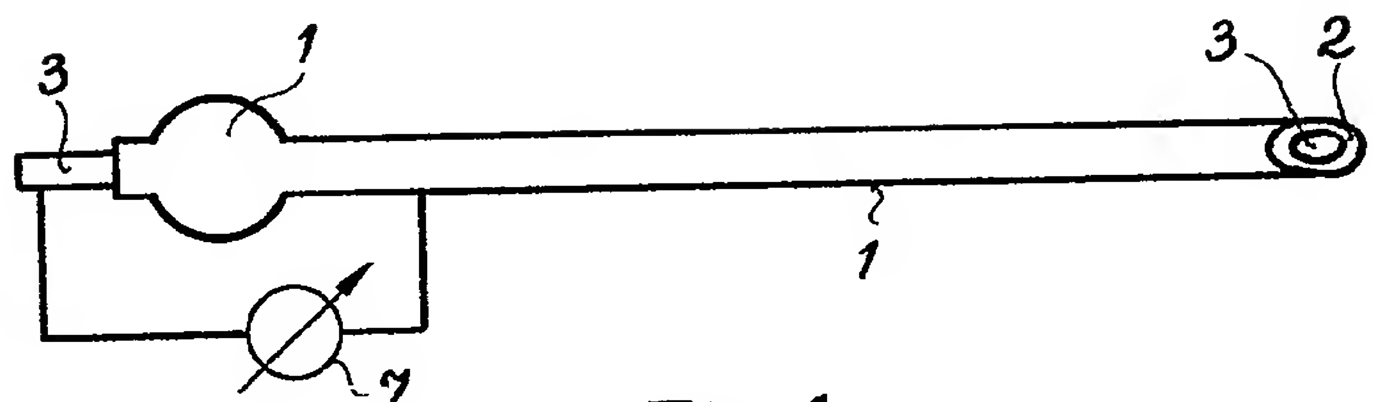

Fig. 1